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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,739	12/30/2004	Antoine LaFont	29644/04002	7985

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EXAMINER	
ANDERSON, GREGORY A	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,739	LAFONT ET AL.	
	Examiner	Art Unit	
	Gregory A. Anderson	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *11-18 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01202005, 01282005, 06222005, 09122007.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 26 September 2007 is acknowledged. The traversal is on the ground(s) that consideration of Group II. along with Group I. does not present a serious burden to the examiner. Upon review of the claims associated with Group II. the examiner deemed the arguments with traverse to be persuasive, and therefore claims 19-23 have been examined along with claims 1-10.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-18 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 26 September 2007.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 7-9 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafont et al. 5,957,975.

Regarding claim 7: Lafont discloses a method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, comprising: providing a hollow, cylindrical device comprising a wall having slits, openings, or voids therein, wherein the hollow cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent (Fig. 4); heating the polymeric cylindrical device to a temperature close to or above the glass transition temperature while expanding the tube to the final predetermined diameter (Col. 9 ll. 15-31); mounting the cylindrical device on a support for maintaining the cylindrical device at the final predetermined diameter (Col. 9 ll. 15-31); heating the mounted cylindrical device to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of pervious processing of the polymeric device (Col. 8 ll. 20-35); rapidly cooling the polymeric cylindrical device at a temperature below the glass transition temperature of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter (Col. 8 ll. 31-35); mounting the educated polymeric cylindrical device on an inflatable balloon catheter (Col. 8 ll. 47-50); Reducing the diameter of the cylindrical device by heating the cylindrical device to a temperature at or slightly above the glass transition temperature of the polymer while evenly supplying pressure on the exterior surface of the wall of the cylindrical device (Col. 8 ll. 27-31); and the rapidly cooling the cylindrical device below the glass transition temperature of the polymer (Col. 8 ll. 31-35) to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent (Col. 8 ll.

47-51) which is substantially resistant to relaxation-related recoil when implanted into the lumen (Col. 6 ll. 66-67, Col. 7 l.1).

Regarding claim 8: Lafont et al. discloses the stent formed from a PLAGA polymer (Col. 5 ll. 14-44).

Regarding claim 9: Lafont et al. discloses the wall thickness of the cylindrical device is substantially the same before and after step (g) (Fig. 4).

Regarding claim 22: lafont et al. discloses a method for preparing a degradable and bioresorbably polymeric stent that is resistant to relaxation-related recoil when implanted (Col. 6 ll. 66-67, Col 7 l. 1), comprising: providing a hollow cylindrical device comprising a wall having openings therein, wherein the hollow cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent (Fig. 4); heating the polymeric cylindrical device to a temperature close to or above the glass transition temperature of the polymer while expanding the tube to the final predetermined diameter (Col. 9 ll. 16-31); mounting the cylindrical device on a support for maintaining the cylindrical device at the final predetermined diameter (Col. 9 ll. 16-31); heating the mounted cylindrical device to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device (Col. 8 ll. 20-35); and rapidly cooling the polymeric cylindrical device at a temperature below the glass transition temperature of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having memory of the final predetermined diameter (Col. 8 ll. 20-35).

Regarding claim 23: Lafont et al. discloses the stent formed from a PLAGA polymer (Col. 5 ll. 14-44).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. 4,950,258 in view of Lafont et al.

Regarding claim 1: Kawai et al. discloses: heating a polymeric cylindrical device which is at a final predetermined radial diameter and wall thickness to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device (Col. 3 ll. 57-65, Col. 4 ll. 2-13), wherein the polymeric cylindrical device has a wall defining a first open end, a second open end, and a channel connecting the first and the second open end (Fig. 5); rapidly cooling the polymeric cylindrical device at a temperature below the glass transition temperature of the polymer to quench the cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape (Col. 3 ll. 57-59, Col. 4 ll. 14-19); reducing the diameter of the cylindrical device by heating the cylindrical device to a temperature at or slightly above the glass transition temperature of the polymer while evenly applying

pressure on the exterior surface of the wall of the cylindrical device (Col. 10 ll. 29-42); and then rapidly cooling the cylindrical device below the glass transition temperature of the polymer.

However, Kawai et al. does not disclose an assembly for delivering a degradable and bioresorbable polymeric stent that is resistant to relaxation-related recoil to a mammalian subject, forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b), wherein the slits, voids, or open spaces are configured to allow a reduction in diameter of the device without substantially altering the wall thickness of the device; and mounting the educated polymeric cylindrical device on an inflatable balloon catheter.

Lafont et al. discloses an assembly for delivering a degradable and bioresorbable polymeric stent (Col. 4 ll. 65-67) that is resistant to relaxation-related recoil (Col.6 ll. 66-67, Col 7 l. 1) to a mammalian subject (Col. 8 47-50), forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b), wherein the slits, voids, or open spaces are configured to allow a reduction in diameter of the device without substantially altering the wall thickness of the device (Fig. 4); and mounting the educated polymeric cylindrical device on an inflatable balloon catheter (Col. 8 ll. 47-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Kawai et al. with the assembly and balloon catheter of Lafont in order to facilitate the delivery of the cylindrical polymeric device to a desired site; and the open spaces of Lafont in order to allow for enlargement of the

lumen of the vessel via the process of arterial remodeling as taught by Lafont et al. (Col. 3 ll. 7-11).

Regarding claim 2: Kawai et al. further does not disclose the cylindrical device mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b).

Lafont et al. discloses the cylindrical device mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b) (Col. 9 ll. 15-31).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the method of Kawai et al. to include the mounting of the device on a support of Lafont et al. in order to aid in preventing the premature collapse of the stent as taught by Lafont et al. (Col. 9 ll. 27-29).

Regarding claim 3: Kawai et al. further discloses the stent being formed from a polymer of PLAGA (Col. 2 ll. 62-68, Col. 3 ll. 1-6).

Regarding claim 4: Kawai et al. further discloses the cylindrical device reduced to a diameter that is less than the diameter of the lumen of the target duct, tube, or vessel (Col. 5 ll. 54-64).

Regarding claim 5: Kawai et al. further discloses the wall thickness of the cylindrical device is substantially the same before and after step (e) (Figs. 4a-5b).

Regarding claim 6: Kawai et al. discloses: a polymeric cylindrical device comprising a wall defining a first open end, a second open end, and a channel connecting the first open end and the second open end, wherein the cylindrical device has a diameter and wall thickness comparable to the final desired diameter and wall

thickness of the stent (Fig. 5a); educating the device by erasing the memory of previous processing of the polymeric device and establishing a memory of the desired diameter (Col. 3 ll. 66-68, Col. 4 ll. 1-13); and quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape (Col. 4 ll. 14-19). Kawai et al. further discloses educating the stent by heating it above the temperature for the original shape memorization.

However, Kawai et al. does not disclose the education is achieved by heating the device to a temperature at least 8.degrees C above the glass transition temperature of the polymer; forming slits, voids, or open spaced in the wall of the polymeric cylindrical device before or after the device is educated; mounting the educated polymeric cylindrical device on an inflatable balloon catheter; crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the glass transition temperature of the polymer; and then rapidly cooling the cylindrical device below the glass transition temperature of the polymer to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to relaxation-related recoil.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the heating temperature of Kawai et al. since it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Lafont et al. discloses an assembly for delivering a degradable and bioresorbable polymeric stent (Col. 4 ll. 65-67) that is resistant to relaxation-related recoil (Col.6 ll. 66-67, Col 7 l. 1) to a mammalian subject (Col. 8 47-50), forming slits, voids, or open spaces in the wall of the polymeric cylindrical device before the device is educated (Fig. 4); mounting the educated polymeric cylindrical device on an inflatable balloon catheter (Col. 8 ll. 47-50); crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the glass transition temperature of the polymer (Col. 8 ll. 14-35); and then rapidly cooling the cylindrical device below the glass transition temperature of the polymer (Col. 8 ll. 31-32).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Kawai et al. with the assembly and balloon catheter of Lafont in order to facilitate the delivery of the cylindrical polymeric device to a desired site; and the open spaces of Lafont in order to allow for enlargement of the lumen of the vessel via the process of arterial remodeling as taught by Lafont et al. (Col. 3 ll. 7-11).

Regarding claim 19: Kawai et al. discloses a method for preparing a degradable and bioresorbable polymeric stent for implantation into the lumen of a tube, duct, or vessel of a mammalian object, comprising: heating a polymeric cylindrical device which is at a final predetermined radial diameter and wall thickness to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device (Col. 4 ll. 2-13), wherein the polymeric device has a wall defining a first open end, a second open

end, and a channel connecting the first and the second open end (Fig. 5a); and rapidly cooling the polymeric cylindrical device at a temperature below the glass transition temperature of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape (Col. 4 ll. 14-33).

However, Kawai et al. does not disclose forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b), wherein the stent is resistant to relaxation-related recoil when deployed in the blood vessel of a subject.

Lafont et al. discloses forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) (Fig. 4), wherein the stent is resistant to relaxation-related recoil when deployed in the blood vessel of a subject (Col. 6 ll. 66-67, Col. 7 l. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Kawai et al. with the forming of slits of Lafont et al. in order to allow for enlargement of the lumen of the vessel via the process of arterial remodeling as taught by Lafont et al. (Col. 3 ll. 7-11).

Regarding claim 20: Kawai et al. further does not disclose the cylindrical device mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b).

Lafont et al. discloses the cylindrical device mounted on a support for maintaining the diameter and shape of the device during step (a) and step (b) (Col. 9 ll. 15-31).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the method of Kawai et al. to include the mounting of the device on a support of Lafont et al. in order to aid in preventing the premature collapse of the stent as taught by Lafont et al. (Col. 9 ll. 27-29).

Regarding claim 21: Kawai et al. further discloses the stent being formed from a polymer of PLAGA (Col. 2 ll. 62-68, Col. 3 ll. 1-6).

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafont et al.

Lafont et al. discloses a method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, comprising: providing a polymeric cylindrical device comprising a wall defining a first open end, a second open end, and a channel connecting the first open end and the second open end, and having open spaces for permitting expansion and contraction of the device without substantially altering the thickness of the wall, wherein the cylindrical device has a radial diameter that is less than the final desired diameter of the stent (Fig. 4), expanding the polymeric device to the final diameter while heating to a temperature close to or above the glass transition temperature of the polymer (Col. 9 ll. 16-31), educating the device by erasing memory of previous processing of the polymeric device and establishing a memory of the desired diameter, wherein such education is achieved by heating the device, which is mounted on a support (Col. 9 ll. 16-31), quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter and shape (Col.

8 ll. 31-32), mounting the educated polymeric cylindrical device on an inflatable balloon catheter (Col. 8 ll. 47-50), crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the glass transition temperature of the polymer (Col. 8 ll. 20-35), and then rapidly cooling the cylindrical device below the glass transition temperature of the polymer (Col. 8 ll. 31-35) to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent (Col. 8 ll. 47-51) which is substantially resistant to relaxation-related recoil when implanted (Col. 6 ll. 66-67, Col. 7 l. 1).

However, Lafont et al. does not disclose the temperature of heating being at least 8 degrees C above the glass transition temperature of the polymer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the heating temperature of Lafont et al. since it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory A. Anderson whose telephone number is (571) 270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/